Rejections under 35 U.S.C. §103(a)

On pages 2-6 and 7-10 of the Official Action, in paragraphs 3, 5, and 7, Claims 1-5, 7-16, 20, and 22 have again been rejected under 35 U.S.C. §103(a) as being unpatentable over Hendrickson et al. (Hendrickson) in view of Gibson et al. (Gibson). On pages 6-7, in paragraph 4, Claim 6 has again been rejected under 35 U.S.C. §103(a) as being unpatentable over Hendrickson in view of both Gibson and Kawazoe et al. (Kawazoe). On pages 8-9, in paragraph 6, Claims 17-19 have again been rejected under 35 U.S.C. §103(a) as being unpatentable over Hendrickson in view of Gibson and further in view of Gold et al. (Gold).

Applicants have canceled Claims 1, 3, 6-7, 15 and 22, thereby rendering the rejection of these claims moot. With respect to Claims 2, 4-5, 8-14, and 16-20, Applicants have amended these claims to depend from independent Claim 23, which has not been included in this rejection. As a result, Applicants submit these claims are in condition for allowance. Consequently, Applicants respectfully request that the Examiner reconsider and withdraw these rejections.

Rejection under 35 U.S.C. §103(a)

The claimed invention is directed to a method for quantitating or detecting a target compound in a sample in which a capture antibody binds to the target compound and an aptamer detector molecule is then used to bind to the antibody:target complex. The amount or presence of the target compound is determined by amplifying the aptamer detector molecule. This method is not disclosed or suggested by Hendrickson, Gibson and/or Kawazoe, alone or considered together. These references do not suggest using an aptamer detector molecule and quantifying or detecting the target by amplifying the aptamer.

For these reasons, the rejection of Claim 23 under 35 U.S.C. §103(a) as being unpatentable over Hendrickson in view of both Gibson and Kawazoe is believed to be unsustainable and should be withdrawn.

More specifically, Hendrickson teaches an immuno-PCR assay method. In the immuno-PCR method of Hendrickson, the detector or reporter molecule is a "Reporter Antibody" having a DNA label (a DNA-antibody conjugate) as shown in Figure 2. The antibody portion binds the target and the DNA portion is amplified for detection and reporting. Hendrickson does not teach or suggest using an aptamer as the binding and reporting molecule. This deficiency of Hendrickson is not overcome by combining the primary reference with Kawazoe.

Kawazoe disclose an assay using a DNA aptamer that is labeled with fluorescein as a reporter molecule (a FITC-aptamer conjugate). See, e.g., the Abstract of Kawazoe and page 873. The fluorescein label portion is used for detection and/or quantitation. The DNA aptamer portion is used to bind to a target or substrate. Combining Hendrickson and Kawazoe, one might be led to modify the teaching of Hendrickson by replacing the DNA-antibody conjugate used by Hendrickson with the FITC-aptamer conjugate used by Kawazoe. However, this does not provide the method of the present invention.

Gibson teaches conventional RT-PCR to quantitate RNA. Combining the teachings of Hendrickson and Gibson, one might be led to amplify the DNA-antibody conjugate of Hendrickson using RT-PCR; however, this is not the same as the present invention in which an aptamer is the binding/reporting molecule and the aptamer itself is then amplified. Combining Kawazoe with Hendrickson/Gibson, one might be led to replace the DNA-antibody conjugate of Hendrickson with the FITC-aptamer conjugate of Kawazoe and then use RT-PCR as suggested by Gibson. However, the use of RT-PCR with a FITC labeled reporter is not suggested.

Combining the disclosures of all three references does not, therefore, suggest the present invention.

In the present invention, the aptamer is not labeled. The aptamer functions both to bind the target and is amplified to quantitate or detect the target. There is no teaching or suggestion in Hendrickson, Gibson and/or Kawazoe to use an unlabeled molecule that provides both binding and quantification as in the present invention.

The Examiner asserts that it would have been obvious to replace the labeled antibody of Hendrickson with the aptamer of Kawazoe because Kawazoe teach several advantages of aptamers over antibodies. As discussed above, however, Kawazoe teach using a labeled DNA aptamer. Thus, replacing the labeled antibody of Hendrickson with the labeled aptamer of Kawazoe as suggested by the Examiner would result in the presence of a labeled DNA aptamer in the immuno-complex (e.g., capture molecule:target molecule:labeled DNA aptamer). This is not the ternary complex of the presently claimed invention. As discussed above, there is no teaching or suggestion of using an unlabeled aptamer as in the present invention in any of the cited references. Thus, Applicants submit that even if the references were combined in the manner suggested by the Examiner, the combination would not result in the present invention. Further, Applicants submit that there is also no teaching or suggestion in the Examiner's cited references to replace the labeled antibody of Hendrickson with a non-labeled aptamer. Kawazoe does not teach the use of an unlabeled aptamer. Thus, there is no suggestion of the present invention by reading the disclosures of Hendrickson, Gibson, and Kawazoe.

In view of the above, Applicants submit that the presently claimed invention is not obvious over Hendrickson in view of Gibson and/or Kawazoe and respectfully request that the Examiner reconsider and withdraw this rejection.

CONCLUSION

In light of the above, Applicants believe that this application is now in condition for allowance and therefore request favorable consideration. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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